



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, DC 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/002,443	01/02/98	SUTTER	G GSF97-06

DAVID E BROOK  
HAMILTON BROOK SMITH & REYNOLDS  
TWO MILITIA DRIVE  
LEXINGTON MA 02173

HM12/0923

EXAMINER

ZEMAN, M

ART UNIT

PAPER NUMBER

1643

9

DATE MAILED:

09/23/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/002,443

Applicant(s)

SUTTER ET AL.

Examiner

Mary K Zeman

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 April 1998.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-30 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 14) ☐ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_\_

Art Unit: 1643

*Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to recombinant MVA viruses, classified in class 435, subclass 320.1.
- II. Claims 12, 21, 22, 23 and 28, drawn to uses of recombinant MVA viruses, classified in class 424, subclass 184.1.
- III. Claims 13-16, drawn to cells infected with MVA virus and their use, classified in class 435, subclass 230.1+.
- IV. Claims 17-20, drawn to cells infected with MVA virus and another non-native nucleic acid, and their use, classified in class 435, subclass 230.1.
- V. Claim 24, drawn to methods of preventing or treating AIDS, classified in class 424, subclass 188.1.
- VI. Claim 25, drawn to methods of preventing melanomas, classified in class 424, subclass 277.1.
- VII. Claims 26-27, drawn to a two part vaccine, classified in class 435, subclass 320.1.
- VIII. Claims 28-30, drawn to particular MVA viruses having particular properties, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II, IV, V & VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

Art Unit: 1643

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant virus can be used for in vitro expression of viral or non-viral proteins.

Inventions I and III are related in that the cells of invention III are infected with the virus of Invention I, however these cells are a differing composition, being used for differing purposes, and the methods have different steps to different ends.

Inventions I and VII are separate and distinct as they are two differing compositions. Invention I is drawn to a recombinant virus, while Invention VII has additional components.

Inventions I and VIII are separate and distinct, as the viruses of invention VIII have differing properties not set forth in the claims of invention I.

Invention II is separate and distinct from Invention III and IV as Invention II is drawn to the use of a virus, while Inventions II and IV are drawn to the use of infected cells. These are differing biological entities having differing biochemical and immunological properties.

Invention II is separate and distinct from Inventions V and VI as invention II is not drawn to the treatment or prevention of a particular disease, the target populations are different for each invention, and the standard of enablement is also different.

Invention II is separate and distinct from Invention VII as it is a differing chemical composition. Invention II is drawn to use of a recombinant virus, while Invention VII has additional components.

Invention II is separate and distinct from Invention VIII as the viruses of invention VIII have differing properties not set forth in the claims of invention II.

Art Unit: 1643

Invention III is separate and distinct from Invention IV as the cells are infected or transfected with differing vectors or viruses, rendering them separate and distinct compositions having separate biochemical properties.

Invention III is separate and distinct from Inventions V and VI as the cells of invention III are not used in the methods of Inventions V and VI.

Invention III is separate and distinct from invention VII as the cells of invention III cannot produce the vaccine of invention VII.

Invention III is separate and distinct from invention VIII as the cells of invention III are a differing biochemical entity from the viruses of invention VIII.

Invention IV is distinct from invention V and VI as the cells of invention IV are not used in the methods of inventions V and VI.

Invention IV is separate and distinct from Invention VII as invention IV is drawn to cells while Invention VII is drawn to a two component vaccine.

Invention IV is separate and distinct from invention VIII as invention IV is drawn to cells, a differing composition of matter than the viruses of Invention VIII

Invention V is separate and distinct from Invention VI as each invention is drawn to the prevention or treatment of two very different disease states, one a viral infection, the other a cancer. Each Invention would have a differing target population.

Invention V & VI are separate and distinct from Invention VII as Invention V & VI are method claims and Invention VII is drawn to a vaccine composition.

Art Unit: 1643

Invention V & VI are separate and distinct from Invention VIII as invention V & VI are method claims, while Invention VIII is drawn to virus compositions.

Invention VII is separate and distinct from Invention VIII as they are drawn to differing compositions of matter having differing properties and different uses.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner, can be reached on (703) 308-1032.

The fax number for this Art Unit is (703) 305-7401.

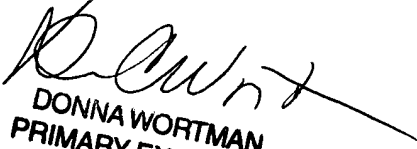
Application/Control Number: 09/002,443

Page 6

Art Unit: 1643

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz  
September 21, 1999

  
DONNA WORTMAN  
PRIMARY EXAMINER